

**REMARKS**

Claims 1-26 were pending in the application. Claims 1, 24, 25 and 26 have been amended to fix minor typographical errors. Claims 8 and 20 have been amended to clarify the invention. Claim 27 is new.

*No new matter has been added.* Support for new claim 27 can be found, at least, in the originally filed specification on page 5, fourth paragraph.

**Objection to the Claims**

In response to the Examiner's objection the comma in between the words "comprising" and "administering" in claims 1, 24, 25 and 26 has been removed.

**Claim Rejections - 35 USC § 112, Second Paragraph**

The Examiner has rejected claims 1-23 as allegedly being indefinite. In particular the Examiner is of the opinion that the phrase "in need thereof" is indefinite because, "it is unclear if the patient is in need of the recited treatment (i.e., treatment of radiation induced enteritis) or is in need of the recited compound in the recited step of administration (i.e., administration of balsalazide). Applicant respectfully disagrees.

MPEP § 2173.02 states, in part, that "[t]he essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity." Definiteness of claims is not to be analyzed in a vacuum, but rather in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

(*Id.*). "The test for definiteness under the second paragraph of 35 U.S.C. § 112 is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.' *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986)" (*Id.*).

Applicants draw the Examiner's attention to page 5, third and fourth paragraphs of the originally file specification;

Subjects in need thereof include subjects that will undergo radiation therapy, either alone or in combination with other pelvic therapies that could induce enteritis. This need may be apparent prior to undergoing radiation therapy, chemotherapy, a pelvic surgical procedure or a combination of therapies; subjects undergoing radiation therapy, chemotherapy, a pelvic surgical procedure or a combination of therapies; and subjects post radiation therapy, chemotherapy, a pelvic surgical procedure, or a combination of therapies. For example, subjects may be about to undergo, may be undergoing, or have undergone radiation therapy in combination with chemotherapy or a surgical procedure.

Also included are subjects who are or who may be susceptible to enteritis. Subjects may be suffering from, for example, gastrointestinal malignancies, including colorectal, appendiceal, anal, or small bowel cancers; urogenital malignancies, including prostate, bladder, testicular, or penile cancers; gynecologic malignancies, including cervical, endometrial, ovarian, vaginal, or vulvar cancers; or osteogenic and other sarcomatous malignancies in which pelvic structures are involved.

Applicants respectfully submit that the claims are indeed definite at least because one of skill in the art would understand what is claimed when the claims are read in light of the passages recited above. Thus, in view of the passages above, it is clear to one of skill in the art that a subject in need includes subjects that will undergo radiation therapy, chemotherapy and/or surgery.

The Examiner has also rejected claims 8 and 20 as allegedly being indefinite. Applicants respectfully disagree. However, solely in the interest of expediting prosecution of the instant application, Applicants have amended claims 8 and 20 by replacing the term “including” with the phrase “selected from.”

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of these rejections.

#### **Claim Rejections - 35 USC § 102**

The Examiner has rejected claims 1-3, 10 and 24-26 as being anticipated inherently by Johnson *et al.*, (WO 95/18622; 1995) under 35 USC § 102(b). The Examiner asserts that in view Johnson *et al.*, that, “such a therapeutic effect would have been necessarily present in the method described by Johnson *et al.*, because Johnson *et al.*, teaches a product that is identical to

that instantly claimed for administration (*i.e.*, a composition comprising a therapeutically effective amount of balsalazide in the amounts instantly claimed) to the same subject (*i.e.*, a subject suffering from colon cancer) and, thus, must also possess this same newly recognized property described by the Applicant, absent factual evidence to the contrary, because products of identical chemical composition used in an identical manner in an identical host cannot have mutually exclusive properties. MPEP §2112.” Applicants respectfully disagree.

As a preliminary matter Applicants would like it noted that the instant application is the U.S. national phase of international application PCT/US2005/018757. Applicants bring to the Examiner’s attention the fact that U.S. Patent No. 5,498,608 was cited in the International Search Report of the instant application as a category “A” reference, *i.e.* a document defining the general state of the art which is not considered to be of particular relevance. U.S. Patent No. 5,498,608 is the U.S. national phase of Johnson *et al.*, WO 95/18622.

Johnson *et al.*, discloses a method of treating colon cancer by administration of balsalazide. In comparison, the instantly claimed invention is directed to a method of treating radiation induced enteritis comprising administering to a subject in need thereof-a therapeutically effective amount of balsalazide. Applicants respectfully submit that colon cancer and radiation induced enteritis are different diseases. Accordingly, the instantly claimed method would not be used to treat the “same subject” as asserted by the Examiner.

Accordingly, withdrawal of this rejection is requested.

### **Claim Rejections - 35 USC § 103**

The Examiner has rejected claims 1, 4-6, 8-13, 16-18 and 20-26 under 35 USC §103(a) as allegedly being unpatentable over Johnson *et al.*, (WO 95/18622; 1995) in view of Podolsky (U.S. Patent Application Publication No. 2003/0078205; 2003). The Examiner asserts that, “Johnson *et al.*, fails to teach (1) the concomitant application of radiotherapy to the subject with colon cancer and the resultant treatment of or protection against radiation induced enteritis, mucosal injury to the colon and/or colorectal inflammation (claims 1 and 24-26); or (2) the frequency and administration of balsalazide (claims 4-6, 9, 11, 16-18, 21 and 23). The Examiner relies on Podolsky to cure these alleged deficiencies and states, “[t]hus, Johnson *et al.*, in view of Podolsky provides a clear teaching, suggestion and/or motivation to combine the balsalazide composition of Johnson *et al.*, with radiotherapy as disclosed by Podolsky for the treatment of colon cancer.” Applicants respectfully disagree.

The instant claims are directed to methods of treating radiation induced enteritis comprising administering to subjects in need thereof a therapeutically effective amount of balsalazide; methods of protecting against radiation induced enteritis comprising administering to subjects before, during, and/or after undergoing radiation therapy a therapeutically effective amount of balsalazide; methods of protecting against radiation induced injury to the mucosa of the colon comprising administering to subjects before, during, and/or after undergoing radiation therapy a therapeutically effective amount of balsalazide; and methods of protecting against radiation induced colorectal inflammation comprising administering to subjects before, during, and/or after undergoing radiation therapy a therapeutically effective amount of balsalazide.

Johnson is described *supra*. Applicants submit that according to its abstract, Podolsky describes compositions and methods for treating and preventing distal bowel disease by rectal administration of intestinal trefoil factors. The intestinal trefoil factors can be administered either alone or in combination with one or more anti-microbial agents, anti-inflammatory agents or analgesics. The second therapeutic agent that may be administered with the intestinal trefoil factors includes a large number of substances, among them 5-aminosalicylate (5-ASA) derivatives such as sulfasalazine, mesalamine, olsalazine and balsalazide. However, while Podolsky discloses administration of a 5-ASA derivative (*e.g.* balsalazide) with intestinal trefoil factors for treating distal bowel disease, any teaching of balsalazide or 5-ASA derivatives is mentioned in the context as useful for treating inflammatory bowel diseases such as Crohn's Disease and ulcerative colitis. It is clear that Podolsky contemplates the use of intestinal trefoil factors for treating or preventing distal bowel disease while balsalazide, if present, is contemplated for its separate therapeutic benefit for treating inflammatory bowel disease. There is thus no teaching or suggestion in Podolsky for treating radiation-induced enteritis with balsalazide. Accordingly, the claims are not obvious over the combination of Johnson *et al.* and Podolsky.

In view of the foregoing, withdrawal of this rejection is requested.

**SUMMARY**

In view of the amendments and remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 449-6500.

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